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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A Request for Continued Examination under 37 CFR § 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on August 12, 2009, has been entered.

Claims 1-8 are pending in the instant application; claims 3 and 4 are withdrawn as being directed to a non-elected species; claims 1, 2 and 5-8 are the subject of the Office Action below.

### ***Claim Rejections - 35 USC § 112, first paragraph (New Matter) – Maintained***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 2 and 5-8, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for containing new matter, is maintained. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants arguments have been fully considered, however, are not found persuasive. Amended claim 1 now recites the following:

“an A1+ genotype is indicative of a candidate for treatment with low dose low DRD2 binding atypical antipsychotics and/or SSRIs; and

an A1- genotype is indicative of a candidate for treatment with high dose or high binding DRD2 binding antipsychotics or alternative antidepressant.”

Claim 1, Amendment received on August 12, 2009 (underlining in original)

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Still, these limitations are in direct contradiction to Applicants provisional application (see first paragraph under Summary of the Invention on page 1; see also claim 1 on page 53), their published International Application WO 2005/007871 A2 (paragraph 0004), and the current specification. Specifically, the specification states:

“The invention provides methods of identifying candidate psychiatric patients or patients with movement disorder for treatment with medication that acts at the D2 dopamine receptor. The method comprises determining a patient's D2 dopamine receptor (DRD2) genotype. Patients having the Taq1A (A1) allele (*A1+ allelic status*) ***are candidates for treatment with high dose of high D2 dopamine receptor binding antipsychotics*** and/or SSRIs that influence D2 dopamine receptor density. Patients lacking the Taq1A allele (*A1- allelic status*) ***are not likely to respond well to these SSRIs, and are candidates for treatment with lowdose of low D2 dopamine receptor binding or low dose high D2 dopamine receptor binding atypical antipsychotics.***”

Specification, paragraph 0004 (emphasis added).

The specification provides the following definitions:

“As used herein, “high dose” of medication means more than the chlorpromazine equivalent per kilogram (kg) of body weight (CPZEK) of about 10. (Given an average adult patient body weight of 70 kg.) One mg risperidone is equipotent to 100 mg chlorpromazine, 100 mg thioridazine, or 2 mg haloperidol. For example, a high dose of risperidone is about 6 mg/day or more for an adult patient.

As used herein, “high D2 dopamine receptor binding” or “high binding” antipsychotics means having an affinity for the D2 dopamine receptor exhibiting a  $K_i$  of less than 10 nM, as measured by in vitro radioligand binding (See, .g., Levant, 1997, Pharmacological Reviews, 49(3):231-252). This class of antipsychotic medications is often referred to in the art as “typical” antipsychotics. Representative examples include risperidone (risperidone), flupenthixol, gluphentazine decanoate, zuclopenthixol, haloperidol, thiondazine, thiotthixene and trofluperazine.

As used herein, “low dose” of medication means less than a CPZEK of less than about 7. For example, a low dose of risperidone is less than about 5 mg/day for an adult patient.

As used herein, “low D2 dopamine receptor binding” or “low binding” antipsychotics means having an affinity for the D2 dopamine receptor exhibiting a  $K_i$  of greater than 15 nM, as measured by in vitro radioligand

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binding (See, e.g., Levant, 1997, Pharmacological Reviews, 49(3):231-252). This class of antipsychotic medications is often referred to in the art as "atypical" antipsychotics. Representative examples include Olanzapine and Clozapine."

Specification, paragraphs 0017-0020.

It is still the Examiner's position that Applicants have relied on a selective interpretation of the specification in finding support. Although there is some support in the discussion of the specification that could *possibly* be construed to support the claim language, the direct contradiction of the specification as cited above, and the vague experimental data (e.g., data for Figures 5 and 6), do not clearly convey that the sections of the specification at paragraphs 0004 and 0017-0020 were simply typographical errors.

The rejection is maintained.

### ***Conclusions***

No claim is allowable.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (e.g., if the amendment is not supported *in ipsiis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey S. Lundgren/

Primary Examiner, Art Unit 1639